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PROVISIONAL APPLICATION FOR PATENT COVER SHEET

This is a request for filing a PROVISIONAL APPLICATION FOR PATENT under 37 CFR 1.53(c).

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Additional inventors are being named on the _____ separately numbered sheets attached hereto					
TITLE OF THE INVENTION (500 characters max)					
Coronary Sinus Locator Sheath for Biventricular Pacing					
Direct all correspondence to: CORRESPONDENCE ADDRESS					
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ENCLOSED APPLICATION PARTS (check all that apply)					
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<input type="checkbox"/> Drawing(s) Number of Sheets _____		<input checked="" type="checkbox"/>		Other (specify) <u>Postcard Receipt</u>	
<input type="checkbox"/> Application Data Sheet. See 37 CFR 1.76					
METHOD OF PAYMENT OF FILING FEES FOR THIS PROVISIONAL APPLICATION FOR PATENT					
<input checked="" type="checkbox"/> Applicant claims small entity status. See 37 CFR 1.27.				FILING FEE Amount (\$)	
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The invention was made by an agency of the United States Government or under a contract with an agency of the United States Government.					
<input checked="" type="checkbox"/> No.					
<input type="checkbox"/> Yes, the name of the U.S. Government agency and the Government contract number are: _____					

[Page 1 of 2]

Respectfully submitted,

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Date 2-25-04

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(if appropriate)

Docket Number: 03383-1-2

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Patent Disclosure

Coronary Sinus Locater Sheath for Biventricular Pacing

Introduction

A rapidly growing field in cardiology is the treatment of congestive heart failure with cardiac pacing (biventricular pacing). In biventricular pacing, besides the conventional right atrial and ventricular pacing leads, an additional lead is placed in the coronary sinus and advanced through the vasculature to a position adjacent to the left ventricle. Pacing the left and right ventricles simultaneously has been found to be beneficial in these patients.

Locating the coronary sinus with a catheter is often an arduous task. The coronary sinus is a small hole about 1-2 cm in diameter, located within a few centimeters posterior to the inferior vena cava in the right atrium. Often, the coronary sinus has a small valve (thespian valve), which partly or completely covers the opening. Moreover, in congestive heart failure patients, the heart is hypertrophied, distorting the normal geometry of the heart.

Currently, the coronary sinus is cannulated by introducing a deflectable or fixed-curve sheath or catheter into the right atrium and manipulating the sheath/catheter until the cardiologist “feels” an entry into an orifice. Puffing dye and viewing the dye puff on fluoroscopy make positive verification of entry into the coronary sinus. If a catheter is used, a sheath is then placed over the catheter and the catheter withdrawn. The sheath is then advanced into a branch vein leading to the left ventricle. At this point, a guidewire can be inserted into the sheath to aid in navigation of a suitable venous branch adjacent to the left ventricle. The guidewire is floppy and can be easily manipulated to enter various branches of the coronary sinus vasculature. Once the proper branch is thought to be located, as evidenced by fluoroscopy, a pacing lead with a center lumen suitable for guidewire insertion is advanced over the guidewire to the desired location. At that point, pacing thresholds are determined, and if acceptable the lead is connected to the implanted pulse generator. If they are not acceptable, the lead or guidewire is again manipulated to find a new location. This becomes an iterative procedure until acceptable pacing thresholds are obtained.

Summary of Invention

Locating the Coronary Sinus

Apparatus and means are disclosed for cannulating the coronary sinus with a sheath or catheter. The sheath or catheter has a side port near the distal end where a guidewire can be advanced into the inferior vena cava. The procedure is to advance the sheath/catheter (without guidewire advancement out of the side port) into the inferior vena cava. Fluoroscopy, infrared endoscopic imaging, intracardiac echo or other means verifies placement in the inferior vena cava. Once in the inferior vena cava, the guidewire is advanced out of the side port and the sheath/catheter is retracted into the right atrium, anchored by the guidewire still residing in the inferior vena cava. Anchoring in the inferior vena cava stabilizes the sheath in a position near the coronary sinus. Small manipulations or rotation will orient the catheter/sheath near the coronary sinus. Once the coronary sinus is engaged, the guidewire is retracted from the inferior

vena cava, allowing sheath/catheter to be further advanced through the coronary sinus vasculature.

With an anchored sheath, a variety of locator catheter/guidewire technologies could be used to locate the coronary sinus. They include:

1. An electrophysiology catheter
2. A guide sheath
3. A guidewire
4. Infrared imaging catheter
5. An electromagnetic mapping catheter (e.g. a magnetic catheter operating with the CARTO mapping system by Biosense Webster)
6. an intracardiac echo catheter

After the guide sheath containing one of the above devices is routed to the desirable location adjacent to the left ventricle the following invention can be utilized:

Pacing Threshold Evaluation

Once the sheath is guided to the proper location in the coronary sinus vasculature, pacing thresholds as well as deleterious pacing effects such as phrenic nerve stimulation can be assessed by having two rings on the sheath mimicking pacing electrodes. These electrodes are connected by wires to outside the patient. They are connected to a pacing threshold analyzer. The analyzer is used to determine pacing threshold and phrenic nerve and muscle stimulation potential.

Implantation of Pacing Lead

After a site is examined for its suitability as a pacing site, the catheter is removed. A guidewire is inserted in the sheath and a coronary sinus pacing lead is inserted through the sheath over the guidewire to the distal end to the same location where successful pacing was observed. The sheath and guidewire are then removed leaving the pacing lead in a position suitable for long term pacing. After pacing threshold evaluation, the lead is then connected to the pulse generator.

Detailed Description of the Invention

This embodiment uses the infrared imaging catheter described in US Patent 6178346. The infrared imaging catheter is inserted in a sheath containing the guidewire port about 3-10 cm from the distal end of the sheath. The sheath also has two electrodes near the distal end. The most distal electrode is about 10 square millimeters in surface area. One centimeter back from the most distal electrode is the proximal electrode about 30 square millimeters in surface area. Both electrodes are connected to insulated wires, which extend out the proximal end of the sheath for connection to a pacing analyzer.

Using fluoroscopy or the infrared images, the catheter is guided to the inferior vena cava. Once in the inferior vena cava, the guidewire is then extended. The guidewire may be a traditional guidewire used in navigating vasculature structures or a more rigid device similar to stylets used in pacemaker leads. Once the guidewire is extended, the sheath-catheter is retracted out of the inferior vena cava with the guidewire still in place inside the inferior vena cava. The guidewire now serves as an anchor for the sheath-catheter. The sheath-catheter is then articulated and rotated until the coronary

sinus comes into view. Once in view, the sheath-catheter is advanced into the coronary sinus. Alternatively, the sheath-catheter could have a fixed curve and be rotated to find the coronary sinus. This could be accomplished several ways. The catheter may be telescoped from the sheath into the coronary sinus. Or the sheath-catheter assembly could be advanced into the coronary sinus. Once the coronary sinus has been engaged, the guidewire is withdrawn out of the inferior vena cava and the imaging catheter is used to navigate the coronary sinus vasculature. As the sheath-catheter is advanced, branches will be imaged. The sheath-catheter can be rotated or articulated to enter a particular branch.

Once the sheath-imaging catheter has reached a desirable pacing site, the wires are connected to a pacing analyzer and pacing thresholds are obtained. Phrenic nerve stimulation is evaluated by pacing at 10 volts. If suitable thresholds are found with no phrenic nerve stimulation, the imaging catheter is withdrawn. A stylet is then inserted in the sheath and routed beyond the distal end of the sheath. Over the guidewire, a coronary sinus pacing lead is inserted and advanced to the end of the sheath so that the pacing electrodes are adjacent to the electrodes on the sheath. The sheath is withdrawn and pacing thresholds are again obtained with the pacing lead. If still acceptable, the lead is connected to the pacemaker.

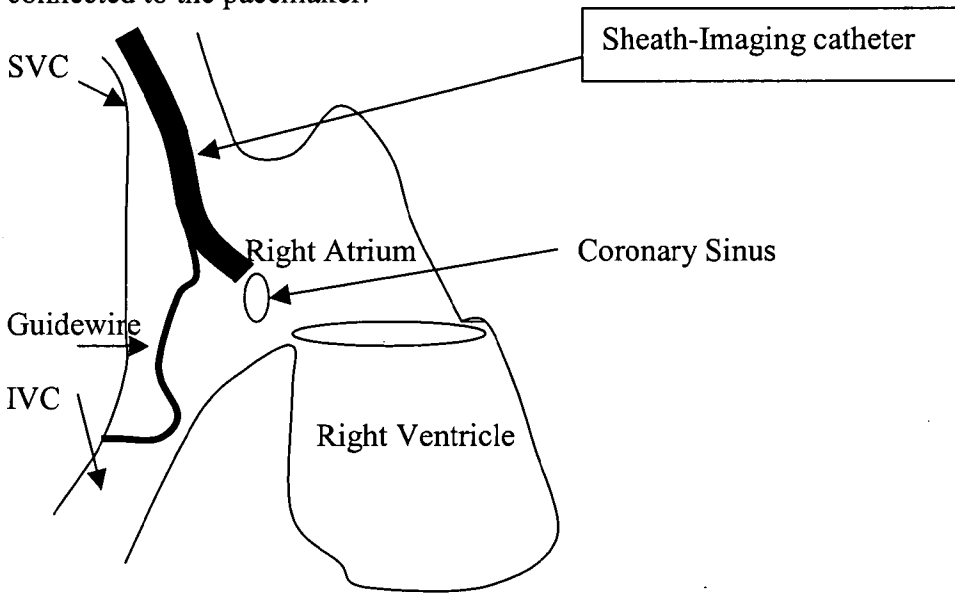


Fig 1: Imaging catheter-sheath with guidewire extending into inferior vena cava

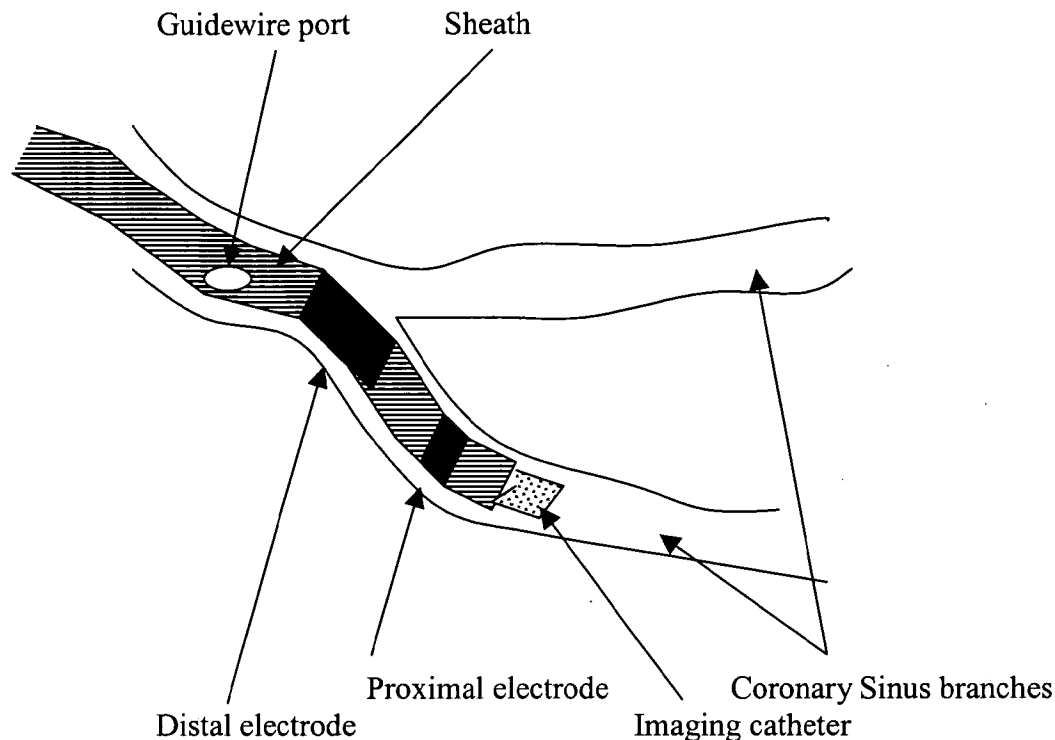


Fig 2: Sheath-imaging catheter inside coronary sinus branch

In this embodiment, an electrophysiology catheter is used. The electrophysiology catheter is inserted in a sheath containing the guidewire port about 3-10 cm from the distal end of the sheath. The sheath also has two electrodes near the distal end. The most distal electrode is about 10 square millimeters in surface area. One centimeter back from the most distal electrode is the proximal electrode about 30 square millimeters in surface area. Both electrodes are connected to insulated wires, which extend out the proximal end of the sheath for connection to a pacing analyzer.

Using fluoroscopy, the catheter is guided to the inferior vena cava. Once in the inferior vena cava, the guidewire is then extended. The guidewire may be a traditional guidewire used in navigating vasculature structures or a more rigid device similar to stylets used in pacemaker leads. Once the guidewire is extended, the sheath-catheter is retracted out of the inferior vena cava with the guidewire still in place inside the inferior vena cava. The guidewire now serves as an anchor for the sheath-catheter. The sheath-catheter is then articulated and rotated until the coronary sinus is engaged by a combination of tactile feel and fluoroscopy. Once in view, the sheath-catheter is advanced into the coronary sinus. This could be accomplished several ways. The

electrophysiology catheter may be telescoped from the sheath into the coronary sinus. Or the sheath-catheter assembly could be advanced into the coronary sinus. Once the coronary sinus has been engaged, the guidewire is withdrawn out of the inferior vena cava and the electrophysiology catheter is used to navigate the coronary sinus vasculature. As the sheath-catheter is advanced, branches will be imaged by puffing dye through the sheath and viewing the fluoroscopic image. The sheath-catheter can be rotated or articulated to enter a particular branch.

Once the sheath-electrophysiology catheter has reached a desirable pacing site, the wires are connected to a pacing analyzer and pacing thresholds are obtained. Phrenic nerve stimulation is evaluated by pacing at 10 volts. If suitable thresholds are found with no phrenic nerve stimulation, the electrophysiology catheter is withdrawn. A stylet is then inserted in the sheath and routed beyond the distal end of the sheath. Over the guidewire, a coronary sinus pacing lead is inserted and advanced to the end of the sheath so that the pacing electrodes are adjacent to the electrodes on the sheath. The sheath is withdrawn and pacing thresholds are again obtained with the pacing lead. If still acceptable, the lead is connected to the pacemaker.

In summary, this invention teaches a method of cannulating the coronary sinus with a sheath-catheter by anchoring in the inferior vena cava with an extendable member from a side port in the sheath. This places the sheath-catheter in the near vicinity of the coronary sinus. The coronary sinus is then engaged and the extendable member is then retracted to permit further advancement in the coronary sinus vasculature. Once an appropriate pacing site is found, the pacing viability can be assessed by pacing with electrodes located near the distal end of the sheath. If acceptable thresholds are obtained, the catheter is removed and replaced with a pacing lead. Finally, the sheath is retracted leaving the pacing lead in place ready for connection to the biventricular pacemaker.

Not all of the disclosed features of the present invention need to be combined in any particular embodiment, and the inventor may regard any subset of the disclosed features as patentable.